

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

In re: ZYPREXA  
PRODUCTS LIABILITY LITIGATION

X

MDL No. 1596

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STATE OF WEST VIRGINIA, ex rel.  
DARRELL V. MCGRAW, JR.,  
Attorney General,

06-CV-5826 (JBW)

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X

Plaintiff,

vs.

ELI LILLY AND COMPANY, INC.,

Defendant.

**CONSENT JUDGMENT AND ASSURANCE OF VOLUNTARY COMPLIANCE**

Plaintiff State of West Virginia, ex rel. Darrell V. McGraw, Jr. (the "State") has filed a Complaint against Defendant Eli Lilly and Company ("Lilly"). Defendant Lilly denies all actionable conduct and allegations of wrongdoing and liability.

Plaintiff State, by its counsel, and Defendant Lilly, by its counsel, have agreed to the entry of this Consent Judgment by the Court without trial or adjudication of any issue of fact or law, and without admission of any wrongdoing or admission of any violation or wrongdoing.

**PREAMBLE**

A. Lilly is willing to enter into this Consent Judgment (the "Judgment") regarding its promotional practices, sampling practices, dissemination of information, and remuneration to Health Care Professionals regarding Zyprexa® in order to resolve the Signatory Attorney General's investigation and this action and arrive at a complete and total settlement and resolution of any disagreement as to the matters addressed in this Judgment and thereby avoid unnecessary expense, inconvenience, and uncertainty; and

3/11/04

B. The Parties have agreed to resolve the issues addressed in this Judgment. Lilly is entering into this Judgment solely for the purpose of settlement and nothing contained herein may be taken as or construed to be an admission or concession of any violation of law or regulation, or of any other matter of fact or law, or of any liability or wrongdoing, all of which Lilly expressly denies. Lilly does not admit any violation of the State Consumer Protection Laws, and does not admit any wrongdoing that was or could have been alleged by any Attorney General before the date of the Judgment under any law. No part of this Judgment, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Lilly. Except in an action brought by the Signatory Attorney General to enforce this Judgment, this Judgment shall not be construed or used as a waiver or limitation of any defense otherwise available to Lilly, including, but not limited to the defense of federal preemption, in other matters, or of Lilly's right to defend itself from, or make any arguments in, any other matter, including, but not limited to, any investigation or litigation relating to the existence, subject matter or terms of this Judgment. This Judgment is made without trial or adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind. It is the intent of the Parties that this Judgment shall not be admissible in any other matter, including, but not limited to, any investigation or litigation, or bind Lilly in any respect other than in connection with the enforcement of this Judgment. No part of this Judgment shall create a private cause of action or confer any right to any third party for violation of any federal or state statute except that the Signatory Attorney General may file an action to enforce the terms of this Judgment. All obligations undertaken by Lilly in this Judgment shall apply prospectively; and nothing contained herein prevents or prohibits the use of this Judgment for purposes of enforcement by the Signatory Attorney General; and

C. The Signatory Attorney General has reviewed the terms of the Judgment and find that such terms serve the public interest; and

D. This Judgment (or any portion thereof) shall in no way be construed to prohibit Lilly from making representations with respect to Zyprexa that are permitted under Federal law or in Labeling for the drug under the most current draft or final standard promulgated by the FDA or the most current draft or final FDA Guidances for Industry, or permitted or required under any Investigational New Drug Application, New Drug Application, Supplemental New Drug Application, or Abbreviated New Drug Application approved by FDA, so long as the representation, taken in its entirety, is not false, misleading or deceptive; and

**IT IS HEREBY ORDERED** that:

**DEFINITIONS**

The following definitions shall be used in construing this Judgment:

1. "Clinically Relevant Information" shall mean information that reasonably prudent clinicians would consider relevant when making prescribing decisions regarding Zyprexa.
2. "Consultant" or "Consulting" shall mean a non-Lilly Health Care Professional engaged to advise regarding marketing or promotion of Zyprexa.
3. "Effective Date" shall mean November 1, 2008.
4. "Eli Lilly and Company" and "Lilly" shall mean Eli Lilly and Company, including all of its affiliates, subsidiaries and divisions, predecessors, successors and assigns doing business in the United States.
5. "FDA Guidances for Industry" shall mean draft or final documents published by the United States Department of Health and Human Services, Food and Drug Administration ("FDA") that represent the FDA's thinking on a topic.

6. "Health Care Economic Information" shall mean data and other information relating to the inputs and outcomes of health care therapies and services, including, but not limited to, the price, cost-effectiveness, and quality of life implications of Zyprexa.

7. "Health Care Professional" or "HCP" shall mean any physician or other health care practitioner who is licensed to provide health care services or to prescribe pharmaceutical products.

8. "Labeling" shall mean all FDA-approved labels, which are a display of written, printed, or graphic matter upon the immediate container of any article, and other written, printed, or graphic matters (a) upon any article or any of its containers or wrappers, or (b) accompanying such article.

9. "Lilly Grant Office" shall mean the U.S.-based organization within Lilly responsible for oversight of the grant process, including the acceptance, review, and payment of all non-clinical grant requests.

10. "Lilly Legal" shall mean personnel of the Lilly Law Division or its designee providing legal advice to Lilly.

11. "Lilly Marketing" shall mean Lilly personnel assigned to the Lilly U.S. Zyprexa marketing team.

12. "Lilly Medical" shall mean Lilly personnel assigned to the Lilly U.S. medical organization.

13. "Lilly Non-Medical" shall mean Lilly personnel other than Lilly personnel assigned to the U.S. Zyprexa medical organization.

14. "Lilly Regulatory" shall mean Lilly personnel or their designee responsible for Lilly's adherence with FDA regulations.

15. "Lilly Sales" shall mean the Lilly sales force responsible for U.S. Zyprexa sales.

16. "Medical Letter" shall mean a non-promotional, scientific communication to address Unsolicited Requests for medical information from HCPs.

17. "Medical Reference" shall mean a non-promotional reference communication that is used for responding to or answering a HCP's Unsolicited Request for medical information.

18. "Off-Label" shall mean a use not consistent with the indications section of the Zyprexa Labeling approved by the FDA at the time information regarding such use was communicated.

19. "Parties" shall mean Lilly and the Signatory Attorney General on behalf of the State.

20. "Promotional," "Promoting" or "Promote" shall mean claims to HCPs about Zyprexa intended to increase sales or attempt to influence prescribing practices of the HCPs.

21. "Promotional Materials" shall mean any item with the product name, logo, or message used to Promote Zyprexa.

22. "Promotional Slide Kit" shall mean Promotional Materials regarding Zyprexa in the form of a slide kit for use in speaker programs.

23. "Promotional Speaker" shall mean a non-Lilly HCP speaker used to Promote Zyprexa.

24. "Reprints Containing Off-Label Information" shall mean articles or reprints from a peer reviewed journal or reference publication describing an Off-Label use of Zyprexa.

25. "Signatory Attorney General" shall mean the Attorney General for the State of West Virginia, or his authorized designee, who has agreed to this Judgment on behalf of the State.

26. "State" shall mean the State of West Virginia.

27. "Unsolicited Request" shall mean a request for information regarding Zyprexa from a HCP communicated to an agent of Lilly that has not been prompted.

28. "Zyprexa®" shall mean all FDA approved drug formulations containing olanzapine as its sole active ingredient and Promoted by Lilly.

### **COMPLIANCE PROVISIONS**

#### **I. Promotional Activities**

A. Lilly shall not make any written or oral claim that is false, misleading or deceptive regarding Zyprexa.

B. For six years from the Effective Date of this Judgment, Lilly shall not Promote Zyprexa for Off-Label uses.

C. For six years from the Effective Date of this Judgment, Lilly shall not present patient profiles/types based on selected symptoms of the FDA-approved indication(s) when promoting Zyprexa, unless:

1. The drug's specific FDA-approved indication(s) being Promoted is/are stated clearly and conspicuously in the same spread (i.e., on the same page or on a facing page) in Promotional Materials as references to selected symptoms.

a. With respect to Promotional Slide Kits:

- (i) Lilly shall state clearly and conspicuously the FDA-approved indication(s) on the same slide in which selected symptoms are first presented;
- (ii) Lilly shall include a short-hand reference to the statement described in Section I.C.1.a.(i) on the same slide as each subsequent reference to selected symptoms (e.g., "See complete list of FDA-approved indications at p. X"); and
- (iii) Lilly shall require any presenter of Lilly's Promotional Slide Kits to present the statement required in Section I.C.1.a.(i), as part of the mandatory slides.

2. Promotional Materials have a reference indicating that the full constellation of symptoms and the relevant diagnostic criteria are available in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV or current version), where applicable.

## **II. Dissemination of Medical Information**

### **A. General Terms**

1. The content of Lilly's communications concerning Off-Label uses of Zyprexa shall not be false, misleading or deceptive.

### **B. Medical Letters and Medical References**

1. The following subsections shall be effective for six years from the Effective Date of this Judgment.

2. Lilly Medical shall have ultimate responsibility for developing and approving the medical content for all Medical Letters and Medical References regarding Zyprexa, including any that may describe Off-Label information. Additional approvals may be

provided by Lilly Regulatory and Lilly Legal. Lilly shall not distribute any such materials unless:

- a. Clinically Relevant Information is included in these materials to provide scientific balance.
- b. Data in these materials are presented in an unbiased, non-Promotional manner.
- c. These materials are distinguishable from sales aids and other Promotional Materials.

3. Lilly Sales and Lilly Marketing personnel shall not develop the medical content of Medical References or Medical Letters regarding Zyprexa. This provision does not prohibit Lilly Sales or Lilly Marketing personnel from suggesting topics for Medical Letters or Medical References.

4. Lilly Sales representatives shall not distribute Medical References or Medical Letters regarding Zyprexa.

5. Lilly shall not knowingly disseminate any Medical Letter describing any Off-Label use of Zyprexa that makes any false or misleading representation regarding Zyprexa or any false or misleading statement concerning a competing product.

C. Responses to Unsolicited Requests for Off-Label information

1. The following subsections shall be effective for six years from the Effective Date of this Judgment.

2. In responding to an Unsolicited Request for Off-Label information regarding Zyprexa, including any request for a specific article related to Off-Label uses, Lilly

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shall advise the requestor that the request concerns an Off-Label use and inform the requestor of the drug's FDA-approved indication(s) and/or dosage and other relevant Labeling information.

3. If Lilly elects to respond to an Unsolicited Request for Off-Label information from a HCP regarding Zyprexa, Lilly Medical personnel shall provide specific, accurate, objective, and scientifically balanced responses. Any such response shall not Promote Zyprexa for an Off-Label use.

4. Any written response to an Unsolicited Request for Off-Label information regarding Zyprexa shall include:

- a. an existing Medical Letter prepared in accordance with Section II.B;
- b. a Medical Letter or other document such as slides prepared in response to the request in accordance with Section II.B; or
- c. a report containing the results of a reasonable literature search using terms from the request.

5. Lilly Non-Medical personnel may not respond in writing to an Unsolicited Request for Off-Label information regarding Zyprexa.

6. Lilly Non-Medical personnel may respond orally to an Unsolicited Request for Off-Label information regarding Zyprexa from a HCP only by informing the HCP of the presence or absence of published studies concerning the Off-Label topic or acknowledge whether the topic is an area of research, and by offering to request on behalf of the HCP that a Medical Letter or other information set forth above in II.C.4 be sent to the HCP in follow up. Lilly Non-Medical personnel shall not characterize, describe, identify, name, or offer any opinions about or summarize any such Off-Label information.

D. Reprints

1. The following subsections shall be effective for six years from the Effective Date of this Judgment.

2. Reprints Containing Off-Label Information

a. Lilly Medical shall be responsible for the identification, selection, approval and dissemination of Reprints Containing Off-Label Information regarding Zyprexa.

b. Reprints Containing Off-Label Information regarding Zyprexa:

(i) shall be accompanied by the full prescribing information for the product and contain a disclosure in a prominent location, which would include the first page or as a cover page where practicable, indicating that the article may discuss Off-Label information; and

(ii) shall not be referred to or used in a Promotional manner.

c. Reprints Containing Off-Label Information regarding Zyprexa may only be disseminated by Lilly Medical personnel to HCPs. Lilly Non-Medical personnel shall not disseminate these materials to HCPs, absent the exception described below in (i).

(i) In the event of an extraordinary circumstance in which there is a clinical necessity to have Lilly Non-Medical personnel disseminate a Reprint Containing Off-Label Information directly to HCPs, the President of LillyUSA may approve a Clinical Necessity Exception to the

prohibition described in Section II.D.2.c. above for that Reprint Containing Off-Label Information.

(ii) If the Clinical Necessity Exception is invoked, Lilly will notify the Signatory Attorney General of its intent to invoke the Clinical Necessity Exception at least 30 business days prior to disseminating through Lilly Sales representatives of any Reprint Containing Off-Label Information on Zyprexa.

(a) If the Signatory Attorney General believes the Reprint Containing Off-Label Information to be disseminated does not meet the Clinical Necessity Exception, then the State will provide Lilly with written notice within 30 business days and provide Lilly an opportunity to discuss its desired use of the Reprint Containing Off-Label Information pursuant to the limited exception.

(b) If the State and Lilly do not come to a resolution, then the State may initiate legal action to prevent the dissemination of the Reprint Containing Off-Label Information by Lilly Non-Medical personnel.

(c) If the State initiates legal action to prevent the dissemination of the Reprint Containing Off-Label Information by Lilly Non-Medical personnel, Lilly

shall not use Lilly Non-Medical personnel to disseminate such Reprint Containing Off-Label Information in that State until the issue has been resolved.

3. Nothing in this Judgment shall preclude Lilly from disseminating reprints which have an incidental reference to Off-Label information. If reprints have an incidental reference to Off-Label information, such reprints shall contain the disclosure required by Section II.D.2.b(i) in a prominent location, as defined above.

E. Health Care Economic Information

1. Nothing in this Judgment shall preclude Lilly from providing Health Care Economic Information to a formulary committee or other similar entity or its members in the course of the committee or entity carrying out its responsibilities for the selection of drugs for managed care or other similar organization pursuant to the standards of FDAMA Section 114 if the information directly relates to an approved indication for Zyprexa and if it is based on competent and reliable scientific evidence.

**III. Continuing Medical Education (CME) and Grants**

A. The following subsections shall be effective for six years from the Effective Date of this Judgment.

B. Lilly shall disclose information about grants, including CME grants, regarding Zyprexa consistent with the current disclosures of the Lilly Grant Office Registry at [www.lillygrantoffice.com](http://www.lillygrantoffice.com) (hereinafter, "LGO website") or as required by applicable law.

1. Lilly shall maintain this information on the LGO website once posted for at least two years and shall maintain the information in a readily accessible format for review by the State upon written request for a period of five years.

C. The Lilly Grant Office shall manage all requests for funding related to CME regarding Zyprexa. Approval decisions shall be made by the Lilly Grant Office alone, and shall be kept separate from the Lilly Sales and Lilly Marketing organizations.

D. Lilly shall not use grants to Promote Zyprexa. This provision includes, but is not limited to, the following prohibitions:

1. Lilly Sales and Lilly Marketing personnel shall not initiate, coordinate or implement grant applications on behalf of any customer or HCP;

2. Lilly Sales and Lilly Marketing personnel shall not be involved in selecting grantees or CME-funded speakers; and

3. Lilly Sales and Lilly Marketing personnel shall not measure or attempt to track in any way the impact of grants or speaking fees on the participating HCPs' subsequent prescribing habits, practices or patterns.

E. Lilly shall not condition funding of a CME program grant request regarding Zyprexa upon the requestor's selection or rejection of particular speakers.

F. Lilly shall not suggest, control, or attempt to influence selection of the specific topic, title, content, speakers or audience for CMEs regarding Zyprexa, consistent with ACCME guidelines.

G. Lilly Sales and Lilly Marketing personnel shall not approve grant requests regarding Zyprexa, nor attempt to influence the Lilly Grant Office to reward any customers or HCPs with grants for their prescribing habits, practices or patterns.

H. Lilly shall contractually require the CME provider to disclose to CME program attendees Lilly's financial support of the CME program and any financial relationship with faculty and speakers at such CME. As part of the disclosure of a financial relationship with

faculty and speakers, Lilly shall contractually require the CME program to identify the URL of a Lilly website, and reference that website as the source for further information concerning grant funding regarding Zyprexa.

I. After the initial delivery of a CME program, Lilly shall not fund the same program, nor shall it provide additional funding for re-distribution of the same program, if it knows that the program's speakers are Promoting Zyprexa for Off-Label uses.

**IV. Payments to Consultants and Speakers**

A. The following subsections shall be effective for six years from the Effective Date of this Judgment.

B. This Section shall apply to U.S. based Consultants and Promotional Speakers to the Lilly Marketing organization.

C. Lilly shall provide to the Signatory Attorney General, in an electronic spreadsheet format, a list of HCP Promotional Speakers and Consultants who were paid by Lilly any taxable income in excess of \$100 for Promotional speaking and/or Consulting performed for Lilly in the U.S., a list of all titles of Promotional presentations made, and the following additional information with respect to each individual Promotional Speaker and/or Consultant:

1. total compensation from Lilly for any Consulting or Promotional speaking fees;
2. total number of Promotional speaking events paid for by Lilly;
3. the state the Promotional Speaker/Consultant has provided to Lilly for contact purposes;
4. the state(s) in which the Promotional Speaker gave the Promotional presentations; and
5. any other compensation from Lilly as set forth in IRS Form 1099.

On or before October 1, 2009, Lilly shall provide the data requested in Nos. 1-4 for the period January 1, 2009-June 30, 2009. On or before January 1, 2010, Lilly shall provide the data requested in Nos. 1-4 for the period July 1, 2009-September 30, 2009. On or before April 1, 2010 and on or before April 1 of each subsequent year, Lilly shall provide the data requested in Nos. 1-5 for the full preceding calendar year.

D. Lilly shall disclose to the Promotional Speaker or Consultant that the information in Section IV.C. above may be disclosed.

**V. Product Samples**

A. The following subsections shall be effective for six years from the Effective Date of this Judgment.

B. Lilly Sales representatives may only sample Zyprexa to a HCP whose clinical practice is consistent with the product's current Labeling. Currently, Lilly samples Zyprexa to the following practices: emergency medicine, family practice, general practice, internal medicine, and psychiatry.

C. If a HCP whose clinical practice is inconsistent with the product's Labeling requests samples, Lilly personnel shall refer the practitioner to 1-800-LillyRx where the practitioner can speak directly with a Lilly representative who will provide answers to their questions about Zyprexa and may provide them with samples if appropriate (i.e., if the physician requests the sample for an on-label use).

**VI. Clinical Research**

A. Lilly shall report research regarding Zyprexa in an accurate, objective and balanced manner as follows or as required by applicable law:

1. To the extent permitted by the National Library of Medicine and as required by the FDA Amendments Act (Public Law No. 110-85), Lilly shall register clinical

trials and submit results to the registry and results data bank regarding Zyprexa as required by the FDA Amendments Act and any accompanying regulations that may be promulgated pursuant to that Act. With respect to Zyprexa, Lilly will register on a publicly accessible website the initiation of all Lilly-sponsored Phase II, III, and IV clinical trials beginning after July 1, 2005 and will post results on a publicly accessible website of all Lilly-sponsored Phase II, III and IV clinical trials that were completed after July 1, 2004.

B. When presenting information about a clinical study regarding Zyprexa in all Promotional Materials, Lilly shall not do any of the following in a manner that causes the Promotional Materials to be false or misleading:

1. present favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;
2. use the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results;
3. use statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations;
4. present the information in a way that implies that the study represents larger or more general experience with the drug than it actually does; or
5. use statistics on numbers of patients, or counts of favorable results or side effects, derived from pooling data from various insignificant or dissimilar studies in a way that



suggests either that such statistics are valid if they are not or that they are derived from large or significant studies supporting favorable conclusions when such is not the case.

**VII. Terms of Payment/Dismissal**

Provided the Court approves this Judgment, and by so doing dismisses this action with prejudice, prior to July 28, 2009, then by July 31, 2009 (and in the event the Court does not supply such approval and dismissal by such deadline, then within three business days following Court approval and dismissal), in consideration for the agreements, promises, and releases provided in this Judgment, Lilly will pay into (i) an account specified by the State, pursuant to separate wire instructions, \$14,750,000.00, which shall be used solely for funding behavioral mental health services; (ii) an account specified by the State's counsel, Richardson, Patrick, Westbrook & Brickman, pursuant to separate wire instructions, \$6,750,000.00, as reasonable attorneys fees and expenses; and (iii) an account specified by the State, pursuant to separate wire instructions, \$1,000,000.00 to the Signatory Attorney General's Consumer Protection Fund, which amount shall be placed in trust and used solely for consumer protection purposes as designated by the Signatory Attorney General, including, but not limited to, restitution, consumer education, credit and bankruptcy counseling and education, conflict resolution programs and costs associated with implementing restitution orders.

**VIII. Conflicts**

A. If subsequent to the Effective Date of this Judgment, the federal government or any state, or any federal or state agency, enacts or promulgates legislation or regulations with respect to matters governed by this Judgment that creates a conflict with any provision of the Judgment and Lilly intends to comply with the newly enacted legislation or regulation, Lilly shall notify the Signatory Attorney General of the same. If the Signatory Attorney General agrees, he/she shall consent to a modification of such provision of the Judgment to the extent necessary to

eliminate such conflict. If the Signatory Attorney General disagrees and the Parties are not able to resolve the disagreement, Lilly shall seek a modification from an appropriate court of any provision of this Judgment that presents a conflict with any such federal or state law or regulation. Changes in federal or state laws or regulations with respect to the matters governed by this Judgment, shall not be deemed to create a conflict with a provision of this Judgment unless Lilly cannot reasonably comply with both such law or regulation and the applicable provision of this Judgment.

B. If, subsequent to the Effective Date of this Judgment, the laws or regulations of the United States, or the draft or final FDA Guidances for Industry, are changed so as to expressly authorize conduct that is expressly prohibited by this Judgment, then such conduct shall not constitute a violation of this Judgment. Provided however, if Lilly intends to engage in the expressly authorized conduct, Lilly shall notify the Signatory Attorney General within 30 business days prior to any change.

**IX. Release**

A. In consideration for the payment provided above, the State releases and forever discharges, to the fullest extent permitted by law, Lilly and all of its past and present subsidiaries, divisions, affiliates, predecessors, successors, and assigns and each and all of their current and former officers, directors, shareholders, employees, agents, contractors, representatives, insurers, and attorneys (collectively, the "Released Parties") of and from the following: all civil, administrative, or criminal claims, charges, causes of action, damages, liens, restitution, disgorgement, reimbursement, overpayment, fines, costs, attorneys fees, penalties, and equitable relief of any nature that the Signatory Attorney General asserted or could have asserted on behalf of the State or in its parens patriae capacity (including, but not limited to any claim and/or any theory under the State's common law and Consumer Protection Acts) against the Released Parties

by reason of any conduct that has occurred at any time up to and including the date of execution of this Agreement in connection with any product containing, in whole or in part, Zyprexa, including the manufacture, testing, marketing, promotion, distribution reimbursement or sale of such product (hereinafter the "Released Claims").

B. Notwithstanding any term of this Agreement, the State specifically does not release any person or entity from any of the following claims or liabilities: (a) any criminal, civil, or administrative claims arising under state revenue codes; (b) any criminal liability not specifically released by this Agreement; (c) any claims based upon obligations created by this Agreement; (d) any claims for personal injury or property damage or for other consequential damages the Released parties have to individual consumers (as opposed to the State); any; or (e) any claims based on a failure to deliver items or services due.

**X. Cure Provision**

A. The Parties agree that the State will provide Lilly with written notice if it believes that Lilly is in violation of any of its obligations under the Judgment ("Notice"). Lilly shall have 30 business days after the date of receipt of the Notice to demonstrate to the State's satisfaction that:

1. Lilly is in compliance with the obligations of the Judgment cited by that State as being violated;
2. the violation has been cured, including, but not limited to, by remedial actions having been taken against an employee for actions inconsistent with this Judgment; or
3. the alleged violation cannot be cured within the 30 business day period, but that: (a) Lilly has begun to take action to cure the violation; (b) Lilly is pursuing such action with due diligence; and (c) Lilly has provided a reasonable timetable for curing the violation.

B. Except as set forth in Section X.D. below, the State may not take any action during the 30 business day cure period. Nothing shall prevent the State from agreeing in writing to provide Lilly with additional time beyond the 30 business days to respond to the notice.

C. The State may not take any action during which a modification request is pending before a court pursuant to Section VIII.A, except as provided for in Section D below.

D. Nothing prohibits the State from taking actions necessary to protect public health and safety as provided by applicable law.

**XI. General Provisions**

A. This Judgment represents the full and complete terms of the settlement entered into by the Parties hereto. In any action undertaken by the Parties, no prior versions of this Judgment, or any prior versions of any of its terms, that were not entered by the Court in this Judgment may be introduced for any purpose whatsoever.

B. This Court retains jurisdiction of this Judgment and the Parties hereto for the purpose of enforcing and modifying this Judgment and for the purpose of granting such additional relief as may be necessary and appropriate

C. This Judgment may be executed in counterparts, and a facsimile or .pdf signature shall be deemed to be, and shall have the same force and effect as, an original signature.

D. All Notices under this Judgment shall be provided to Nina Gussack, Paul Kalb, and the General Counsel of Eli Lilly and Company by Overnight Mail at:

Nina M. Gussack, Esquire  
Pepper Hamilton, LLP  
3000 Two Logan Square  
Eighteenth and Arch Streets  
Philadelphia, PA 19103-2799

Paul E. Kalb, Esquire  
Sidley Austin, LLP  
1501 K Street, N.W.  
Washington, DC 20005

General Counsel  
Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, IN 46285

**STIPULATED AND AGREED TO:**

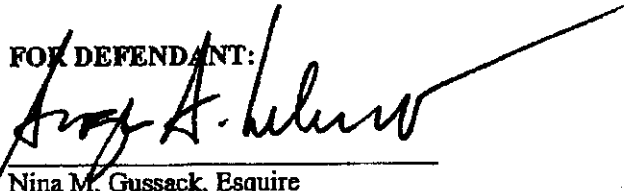
**FOR PLAINTIFF:**

DARRELL V. MCGRAW, JR.  
ATTORNEY GENERAL

*Frances A. Hughes*  
*by Jeanne Young*  
\_\_\_\_\_  
Frances A. Hughes, Esquire  
Chief Deputy Attorney General  
West Virginia Attorney General's Office  
West Virginia State Capitol  
Building 1, Room 26-E  
Charleston, WV 25305  
Telephone No. (304) 558-2021  
Facsimile No. (304) 558-0140

Date: 7-27-09


FOR DEFENDANT:

  
Nina M. Gussack, Esquire  
George A. Lehmer, Esquire  
Pepper Hamilton, LLP  
3000 Two Logan Square  
Eighteenth and Arch Streets  
Philadelphia, PA 19103-2799  
Telephone No. (215) 981-4950  
Facsimile No. (215) 981-4750

Date:

July 27, 2009

FOR DEFENDANT:

  
Michael J. Harrington, Esquire  
Deputy General Counsel  
Lilly Corporate Center  
Indianapolis, IN 46285

Date:

July 27, 2009

*So ordered*  
*Jack B. Went*  
*7/28/09*

**APPROVED AND DISMISSAL WITH PREJUDICE (each of the Parties bearing its own costs) SO ORDERED:**

\_\_\_\_\_  
Honorable Jack B. Weinstein

Date: \_\_\_\_\_, 2009

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